

MANDEL & ADRIANO

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: ANIMAL MODELS OF HUMAN PROSTRATE CANCER PROGRESSION

The specification of which

a. ☐ is attached hereto

b. ☒ was filed on October 15, 1997 as application serial no. 08/951,143 and was amended on (if applicable) (in the case of a PCT-filed application) described and claimed in international no filed and as amended on (if any), which I have reviewed and for which I solicit a United States patent.

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a. ☐ no such applications have been filed.

b. ☒ such applications have been filed as follows:

| FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119 | | | |
|--|--------------------|--------------------------------------|-------------------------------------|
| COUNTRY | APPLICATION NUMBER | DATE OF FILING (day, month, year) | DATE OF ISSUE (day, month, year) |
| | | | |
| ALL FOREIGN APPLICATION(S), IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S) | | | |
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| U.S. PROVISIONAL APPLICATION NUMBER | DATE OF FILING (Day, Month, Year) |
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| 08/732,676 | October 15, 1996 |

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

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SaraLynn Mandel Reg. No. 31,853

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| | | | | |
|----------------------------|----------------------------|---|--------------------------------|---|
| 2 | Full Name Of Inventor | Family Name Sawyers | First Given Name Charles | Second Given Name L. |
| 0 | Residence & Citizenship | City Los Angeles | State or Foreign Country CA | Country of Citizenship USA |
| 1 | Post Office Address | Post Office Address 177 S. Westgate Avenue | City Los Angeles | State & Zip Code/Country CA 90049/USA |
| Signature of Inventor 201: | | | Date: | |
| | | | 3/01/00 | |
| 2 | Full Name Of Inventor | Family Name Klein | First Given Name Karen | Second Given Name A. |
| 0 | Residence & Citizenship | City Los Angeles | State or Foreign Country CA | Country of Citizenship USA |
| 2 | Post Office Address | Post Office Address 174 Denslow Avenue | City Los Angeles | State & Zip Code/Country CA 90049/USA |
| Signature of Inventor 202: | | | Date: | |
| 2 | Full Name Of Inventor | Family Name Witte | First Given Name Owen | Second Given Name N |
| 0 | Residence & Citizenship | City Sherman Oaks | State or Foreign Country CA | Country of Citizenship USA |
| 3 | Post Office Address | Post Office Address 14727 Sutton Drive | City Sherman Oaks | State & Zip Code/Country CA 91403/USA |
| Signature of Inventor 203: | | | Date: | |
| 2 | Full Name Of Inventor | Family Name Reiter | First Given Name Robert | Second Given Name E. |
| 0 | Residence & Citizenship | City Los Angeles | State or Foreign Country CA | Country of Citizenship USA |
| 4 | Post Office Address | Post Office Address 10511 Kinnard Avenue | City Los Angeles | State & Zip Code/Country CA 90024/6017/USA |
| Signature of Inventor 204: | | | Date: | |

§ 1.56 Duty to disclose information material to patentability.

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(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

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| | | | | |
|--|----------------------------|---|--------------------------------|---|
| 2 | Full Name Of Inventor | Family Name Sawyers | First Given Name Charles | Second Given Name L |
| 0 | Residence & Citizenship | City Los Angeles | State or Foreign Country CA | Country of Citizenship USA |
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| Signature of Inventor 201: | | | Date: | |
| 2 | Full Name Of Inventor | Family Name Klein | First Given Name Karen | Second Given Name A |
| 0 | Residence & Citizenship | City Los Angeles | State or Foreign Country CA | Country of Citizenship USA |
| 2 | Post Office Address | Post Office Address 174 Denslow Avenue | City Los Angeles | State & Zip Code/Country CA 90049/USA |
| Signature of Inventor 202: <i>Karen A Klein, PhD</i> | | | Date: <i>3/6/00</i> | |
| 2 | Full Name Of Inventor | Family Name Witte | First Given Name Owen | Second Given Name N |
| 0 | Residence & Citizenship | City Sherman Oaks | State or Foreign Country CA | Country of Citizenship USA |
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| | | | | |
|----------------------------|-------------------------|---------------------|--------------------------|--------------------------|
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| 0 | Residence & Citizenship | City | State or Foreign Country | Country of Citizenship |
| 1 | Post Office Address | Post Office Address | City | State & Zip Code/Country |
| Signature of Inventor 201: | | | Date: | |
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| 0 | Residence & Citizenship | City | State or Foreign Country | Country of Citizenship |
| 3 | Post Office Address | Post Office Address | City | State & Zip Code/Country |
| Signature of Inventor 203: | | | Date: Mar 10, 2000 | |
| 2 | Full Name Of Inventor | Family Name | First Given Name | Second Given Name |
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US, 01/2000 11:21 020330034 MANDL AND ADRIANO PAGE 00

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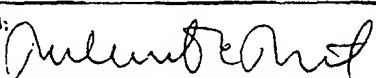
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| | | | | |
|---|----------------------------|---|--------------------------------|---|
| 2 | Full Name Of Inventor | Family Name Sawyers | First Given Name Charles | Second Given Name L. |
| 0 | Residence & Citizenship | City Los Angeles | State or Foreign Country CA | Country of Citizenship USA |
| 1 | Post Office Address | Post Office Address 177 S. Westgate Avenue | City Los Angeles | State & Zip Code/Country CA 90049/USA |
| Signature of Inventor 201: | | | Date: | |
| 2 | Full Name Of Inventor | Family Name Klein | First Given Name Karen | Second Given Name A. |
| 0 | Residence & Citizenship | City Los Angeles | State or Foreign Country CA | Country of Citizenship USA |
| 2 | Post Office Address | Post Office Address 174 Denslow Avenue | City Los Angeles | State & Zip Code/Country CA 90049/USA |
| Signature of Inventor 202: | | | Date: | |
| 2 | Full Name Of Inventor | Family Name Witte | First Given Name Owen | Second Given Name N. |
| 0 | Residence & Citizenship | City Sherman Oaks | State or Foreign Country CA | Country of Citizenship USA |
| 3 | Post Office Address | Post Office Address 14727 Sutton Drive | City Sherman Oaks | State & Zip Code/Country CA 91403/USA |
| Signature of Inventor 203: | | | Date: | |
| 2 | Full Name Of Inventor | Family Name Roster | First Given Name Robert | Second Given Name E |
| 0 | Residence & Citizenship | City Los Angeles | State or Foreign Country CA | Country of Citizenship USA |
| 4 | Post Office Address | Post Office Address 10511 Kinnard Avenue | City Los Angeles | State & Zip Code/Country CA 90024/6017/USA |
| Signature of Inventor 204: | | | Date: | |
|  | | | 3/7/00 | |

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim;
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

NONPROFIT ORGANIZATION

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 C.F.R. 1.9(e) AND 1.27(d)) - NONPROFIT ORGANIZATION

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF ORGANIZATION: The Regents of the University of California
ADDRESS OF ORGANIZATION: 300 Lakeside Drive
22nd Floor
Oakland, California 94612-3550

TYPE OF ORGANIZATION.

- a) ☒ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
- b) ☐ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) AND 501(c)(3))
- c) ☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA -- (NAME OF STATE _____)
(CITATION OF STATUTE _____)
- d) ☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) AND 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA
- e) ☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA -- (NAME OF STATE _____)
(CITATION OF STATUTE _____)

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 C.F.R. 1.9(e) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in regard to the invention, entitled ANIMAL MODELS OF HUMAN PROSTATE CANCER PROGRESSION by inventor(s) Charles Sawyers, Karen Klein, Owen Witte and Robert Reiter described in

- a) ☐ the specification filed herewith.
b) ☐ provisional application serial no. _____, filed _____
c) ☒ non-provisional application serial no. 08/951,143, filed October 15, 1997
d) ☐ patent no. _____, issued _____

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above-identified invention.

If the rights held by the nonprofit organization are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. 1.9(c) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e)

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. 1.27)

NAME UroGenesys
ADDRESS 1701 Colorado Avenue, Santa Monica, California 90404
a) ☐ INDIVIDUAL b) ☒ SMALL BUSINESS CONCERN c) ☐ NONPROFIT ORGANIZATION

NAME _____
ADDRESS _____
a) ☐ INDIVIDUAL b) ☐ SMALL BUSINESS CONCERN c) ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.28(b))

NAME: Emily Waldron
TITLE: Technology Transfer Officer
ADDRESS: UCLA Sponsored Research
1400 Ueberroth Building
405 Hilgard Avenue
Los Angeles, California 90024

SIGNATURE.

DATE:

SMALL BUSINESS**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 C.F.R. 1.9(f) AND 1.27(c)) - SMALL BUSINESS CONCERN**

I hereby declare that I am

- a) ☒ the founder of the small business concern identified below:
 b) ☐ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: UroGenesys
 ADDRESS OF CONCERN: 1701 Colorado Avenue
 Santa Monica, California 90404

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. 121.801-805, and reproduced in 37 C.F.R. 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled ANIMAL MODELS OF HUMAN PROSTATE CANCER PROGRESSION by inventor(s) Charles Sawyers, Karen Klein, Owen Witte and Robert Reiter described in

- a) ☐ the specification filed herewith.
 b) ☐ provisional application serial no. _____, filed _____.
 c) ☒ non-provisional application serial no. 08/951,143, filed October 15, 1997
 d) ☐ patent no. _____, issued _____.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. 1.9(c) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. 1.27)

NAME The Regents of the University of California
 ADDRESS 300 Lakeside Drive, 22nd Floor, Oakland, California 94612-3550
 a) ☐ INDIVIDUAL b) ☐ SMALL BUSINESS CONCERN c) ☒ NONPROFIT ORGANIZATION

NAME _____
 ADDRESS _____
 a) ☐ INDIVIDUAL b) ☐ SMALL BUSINESS CONCERN c) ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.

NAME: Donald B. Rice, Ph. D.
 TITLE: President and CEO
 ADDRESS: 1701 Colorado Avenue, Santa Monica, California 90404

SIGNATURE: Donald B. Rice

Date:

6/8/98